In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0876V

MIKE RODRIGUEZ, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: June 10, 2024

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On February 5, 2021, Mike Rodriguez filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of an influenza ("flu") vaccine received on October 28, 2020, he suffered a left shoulder injury related to vaccine administration ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1); *see also* Amended Petition filed Aug. 23, 2021 (ECF No. 10) (elaborating on the factual allegations and providing citations to the medical records).

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

As set forth in more detail below, I find that Petitioner more likely than not began to experience shoulder pain less than forty-eight (48) hours after vaccination. And based on the lack of any other objections from Respondent along with an independent review of the record, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim – making him entitled to compensation.

I. Procedural History

After Petitioner completed the statutorily required filings, the case was activated and assigned to the "Special Processing Unit" – OSM's forum for cases which are deemed likely to resolve without extensive resources. Activation Order (ECF No. 17). The parties explored the prospect of settlement from July 2023 until they reached an impasse in January 2024. *See generally* ECF Nos. 28 – 38. On March 22, 2024, Respondent filed a Rule 4(c) Report opposing compensation, on the grounds that there is not preponderant evidence of onset within 48 hours, as required by the Table. Rule 4(c) Report (ECF No. 39). Upon reviewing the case file, I have determined that the parties' respective positions regarding onset – and entitlement for the Table SIRVA more generally – were sufficiently developed and therefore ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Findings of Fact and Conclusions of Law - Onset

I have reviewed all of the filings submitted by both parties to date, but focus on the sole disputed issue: onset.

- In October 2019 (a year prior to the relevant vaccination), Petitioner suffered an injury to his opposite *right* shoulder while practicing defensive tactics, as part of his employment as a public safety officer. He attended orthopedics evaluations and physical therapy ("PT") sessions, underwent an MRI arthrogram, and was diagnosed with a right shoulder SLAP tear. In March 2020, Petitioner's right shoulder injury was assessed to be maximally medically improved, and he was released back to full work duty. *See generally* Ex. 5 at 3 – 21 (orthopedics records); *see also* Ex. 8 at 55 – 83 (PT records, reflecting workers' compensation coverage for the left shoulder injury). These records do not reflect any complaints or abnormal findings in the *left* shoulder, however.

- Additionally, a November 2019 internal medicine record provides that Petitioner's complaints included pain in his neck and both arms, left more than right, with associated tingling. This complaint was assessed as an unspecified polyneuropathy, and it was not documented at a subsequent internal medicine encounter in January 2020, *compare* Ex. 4 at 5 – 7, 8 – 9, and there are no other pre-vaccination medical records.

- On October 28, 2020, Petitioner received the subject vaccine in his left deltoid at a Walgreens pharmacy in Las Vegas, Nevada. Ex. 1 at 4 – 6.

- Twenty-one (21) days post-vaccination, on November 18, 2020, at a visit to a new primary care provider ("PCP"), Petitioner wrote on the new patient questionnaire that his chief concern was "flu shot caused injury to shoulder." Ex. 6 at 13. The form did not request the injury's *date*, however. *Id.* During the appointment, a physician recorded that Petitioner "had a flu shot in his left shoulder couple weeks

ago and **subsequently** has had pain located in that area. No other trauma no previous injury." *Id.* at 21 (emphasis added). An exam found that the left shoulder had full range of motion ("ROM") and no impingement signs, but there was area of "fullness" at the injection site, assessed to be consistent with subcutaneous fluid. *Id.* at 22. An ultrasound of the area was unremarkable. *Id.* at 22, 26.

- On December 2, 2020, the same PCP followed up, via telemedicine, on Petitioner's persistent "left shoulder pain which started **after** flu shot." Ex. 6 at 36 (emphasis added). The PCP told Petitioner to return in-person for further evaluation. *Id.* at 37.

- On December 17, 2020, the PCP again recorded that Petitioner was suffering from left shoulder pain "**secondary to vaccination** he received at Walgreens." Ex. 6 at 54 (emphasis added).[4] The PCP ordered an MRI, PT, and an orthopedics referral. *Id.*

- The December 29, 2020, MRI report lists a clinical history of "left shoulder pain **after** receiving a flu shot," and an impression of minimal tendinopathy of the insertion of the infraspinatus tendon. Ex. 8 at 49 (emphasis added).

- On March 27, 2021, Petitioner began PT for his left shoulder. His new patient form lists an onset date of "Oct. 2020." Ex. 8 at 39. The therapist recorded the nature of injury was: "**Oct. 2020 began after injection for flu shot** injured the tendon." *Id.* at 29 (emphasis added). The therapist assessed left shoulder pain, decreased ROM, and weakness. *Id.* Petitioner was offered formal PT twice a week for six weeks, to include instruction on a home exercise program ("HEP"). *Id.* But he attended just eight sessions concluding on May 15, 2021. Ex. 8 at 7 – 20; *see also id.* at 3 – 5 (billing records); *id.* at 51 – 53 (communications log, reflecting appointment cancellations at times due to work and illness). The final PT record, from May 15, 2021, provides that Petitioner had "nearly full ROM throughout the shoulder complex" and pa0in rated 1/10. Ex. 8 at 11 – 12.[5]

- In his September 8, 2021, affidavit, Petitioner recalled: "I received the influenza vaccination in my left shoulder on October 28, 2020… That same date, I began to

[4] The PCP records also provide that Petitioner filed a complaint against Walgreens. Ex. 6 at 36, 54. Petitioner subsequently advised that he did not file a "formal" complaint with Walgreens, rather, he placed a phone call to Walgreens to report his injury, but he did not receive any follow-up correspondence. Pet. Status Report filed Aug. 31, 2022 (ECF No. 23).

[5] Petitioner later confirmed that he did not seek any further treatment beyond this PT session on May 15, 2021, and thus, there are no updated medical records to file. Pet. Status Report filed Aug. 31, 2022 (ECF No. 23).

experience sharp pain my left shoulder…My symptoms began within forty-eight (48) hours of vaccination[.]" Ex. 3 at ¶¶ 4 – 5, 7.

The only issue requiring adjudication is the onset of Petitioner's left shoulder pain. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii). Respondent avers: "Petitioner did not complain of left shoulder pain or seek care for his alleged left shoulder injury for twenty-one [21] days after vaccination. When he did present, Petitioner [reported] that he received a flu shot and 'subsequently' had pain. Based on the record as it stands, the contemporaneous medical records do not demonstrate that there is preponderant evidence of onset of pain within 48 hours of vaccination." Rule 4(c) Report at 4 (internal citations omitted).

Such onset objections are not novel in the SIRVA context – and unpersuasive as well given the evidence. Importantly, "the Vaccine Act does not require that symptoms be recorded within a specific time frame or manner… Indeed, a special master may find that the first symptom or manifestation of onset of an injury occurred 'within the time frame described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation *was not recorded or was incorrectly recorded as having occurred outside such period.*'" *Accetta v. Sec'y of Health & Hum. Servs.*, No. 17-1731V, 2020 WL 3970180, at *5 (Fed. Cl. Spec. Mstr. June 11, 2020) (citing Section 13(b)(2)); *see also, e.g.*, *Werning v. Sec'y of Health & Hum. Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (noting the absence of any affirmative evidence of a different onset).

Within the context of SIRVA claims, it is not uncommon for a patient and/or the medical provider to utilize non-specific terminology while recording onset. But when onset statements in a record are temporally non-specific but otherwise attributed to a vaccination, it is reasonable to conclude the onset was likely close enough in time to vaccination to meet this Table requirement of within 48 hours. *See, e.g.*, *Werning*, 2020 WL 5051154, at *10 (accepting histories of "since" and "after"); *Smallwood v. Sec'y of Health & Hum. Servs.*, No. 18-0291V, 2020 WL 2954958, at *10 (Fed. Cl. Spec. Mstr. Apr. 29, 2020) (reasoning: "The simple fact that Petitioner did not use the phrase 'within 48 hours' does not diminish the impact of these statements"). Here, the medical records reflect Mr. Rodriguez's consistent reporting that his pain began "after" his vaccination, and not after any other inciting event. Moreover, when he was directed to provide a more specific timeframe, he answered "October 2020." His affidavit specifies that his pain began "the same date" as the vaccination. This evidence, considered in its entirety, supports an onset finding in his favor.

It has also been repeatedly observed that SIRVA petitioners often delay treatment, thinking that an injury will resolve on its own. *See, e.g.*, *Smallwood*, 2020 WL 2954958, at *10 (accepting a 54-day initial treatment delay); *Lesher v. Sec'y of Health & Hum. Servs.*, No. 17-1076V, 2020 WL 4522381, at *6 (Fed. Cl. Spec. Mstr. July 2, 2020) (40-day delay). And a twenty-one (21) day timeframe between Mr. Rodriguez's vaccination and his first medical treatment for a shoulder injury is not particularly long. Such a "delay" is not long enough to suggest later generalized reports of pain after vaccination cannot be interpreted as fitting the 48-hour Table requirement.[6] Overall, there is preponderant evidence that the onset of Mr. Rodriguez's left shoulder pain more likely than not occurred within 48 hours of vaccination.

Conclusion and Scheduling Order

Respondent does not raise any other objections to entitlement (*see generally* Rule 4(c) Report), and based on my independent review, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim. 42 C.F.R. §§ 100.3(c)(10)(i, iii, iv). Accordingly, he need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a Table SIRVA following the October 28, 2020, flu vaccine.**

Therefore, the case is now formally in the damages phase. The parties are instructed to adjust their assessments of the claim (given that it is no longer in a settlement posture) and promptly determine whether an informal resolution can be reached.[7]

By no later than Friday, July 26, 2024, Petitioner shall file a Joint Status Report updating on the parties' efforts towards informally resolving damages. If the parties have reached an impasse, the status report shall propose a schedule for either sequential or simultaneous briefing of their respective positions on damages.

[6] At most, the timing of Petitioner's first medical encounter for his shoulder injury is relevant to assessing the initial injury's severity, which would be one factor in assessing an appropriate pain and suffering award.

[7] It is noted that the medical records reference Petitioner's insurance coverage changing, and specific references to Medicaid. *See, e.g.*, Ex. 6 at 62, 66 – 74; Ex. 8 at 4 – 6. But Petitioner has reported that no Medicaid lien is associated with his claim. Pet. Status Report filed Aug. 31, 2023 (ECF No. 30).

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master